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INTEGRATION OF INSTRUMENTATION FOR MEASURING VITAL SIGNS

FINAL REPORT, PHASE I

D. KENT BACKMAN

OCTOBER 31, 1992

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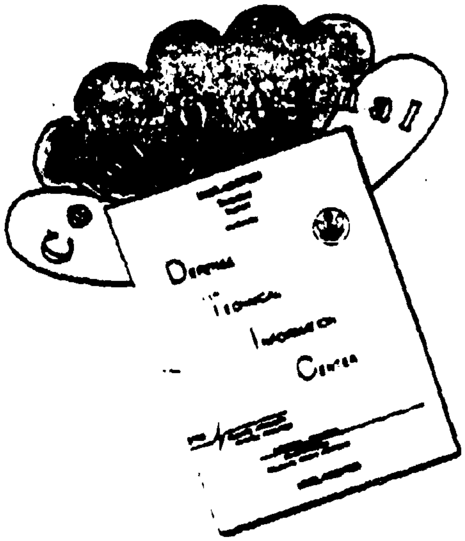

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We completed the review of available techniques and equipment and met with or talked with several representative groups of Army medical staff. In this study a variety of general problems were resolved and several desirable system configurations emerged.

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INTEGRATION OF INSTRUMENTATION FOR MEASURING VITAL SIGNS - FINAL REPORT

I. INTRODUCTION

The original statement of work for the vital signs monitor (VSM) Phase I proposal defined a three step plan:

- **Vital Sign Parameter Determination**

  To determine, by consensus with U. S. Army medical specialists, which parameters must be measured to determine the physiological state of soldiers in the battlefield and during evacuation.

- **Review of VSM Instrumentation**

  To review available diagnostic methods and instrumentation applicable to measuring, evaluating and transmitting vital signs data.

- **New VSM Configuration**

  To propose optimal configurations of equipment particularly suited to monitoring vital signs in the environment described. Of particular concern are accuracy, durability and compliance.

Sarcos completed the review of available techniques and equipment and met with or talked with several representative groups of Army medical staff. In this study a variety of general problems were resolved and several desirable system configurations emerged.

It became apparent that Sarcos could not improve much on portable VSMs such as the Minipack 911 marketed by Pace Teck. That unit fills a market niche and does it well. It is, however, too cumbersome and requires excessive power for battlefield use. Other systems are specifically designed for hospital use or for limited, non-combat physiologic data transmission.

Sarcos determined during the early stages of this project that Army personnel with battlefield and evacuation experience must be consulted. Discussions with: Mr. Charles Paschal, C. O. R., U.S. Army Medical Materiel

Development Activity, U.S. Army Medical Research Acquisition Activity, Fort Detrick, Frederick, MD; Donald Jenkins, M. D., Director, The Borden Institute, Walter Reed Army Medical Center, Bethesda, MD, and General J. Hutton, Chief White House Surgeon, Washington, DC; and, particularly with Major Joseph Hatch, Clinical Consultant, U. S. Army Medical Department, Center and School, Fort Sam Houston, San Antonio, TX., resulted in a data base that provided improved definition of the Army's Battlefield/EVAC VSM system requirements.

Two distinct, optimal VSM system configurations emerged. The Vital Signs Monitor, and a unique new concept, the Life State Monitor. Both monitors are described below:

- **Vital Signs monitor (VSM)**

  One system is required to specifically monitor VS from battlefield to hospital. This unit could be placed on an injured soldiers hand by a medic or buddy and would monitor and optionally transmit VS data. If the soldier's condition changed or deteriorated an alarm would alert medical personnel. Vital signs that were deemed important included SaO_2, electrocardiogram (ECG), respiration rate, and blood pressure. SaO_2 gives a measure of tissue perfusion and, together with respiration, blood pressure and ECG provides an evaluation of a soldiers cardiopulmonary system.

ECG and respiration rate are relatively easy to measure using well known techniques. SaO_2, while not particularly easy to measure, can be determined with established methods. Blood pressure measurement, however, is not so simple. Placing an intra-arterial catheter under combat conditions or during air evacuation is not trivial and conventional cuff and Korotkoff sound detection to measure BP cannot be used in a noisy battlefield or evacuation helicopter environment. Sarcos searched for a non-invasive method that could be derived from only the VS parameters obtained above. Such a method was found and is based on a technique discovered in 1922 by Bramwell and Hill. Basically, the velocity of a pulse wave is a function of arterial elasticity, one of the several parameters that determine blood pressure. Pulse wave velocity can be determined from pulse oximetry and ECG data. The second parameter is heart rate which is easily obtained from the ECG. This approach readily gives change in blood pressure and can be calibrated for actual blood pressure using the soldiers normal blood pressure and PWV data. Since these techniques use optical and electrical signals they are relatively immune to acoustical noise, a major factor in air ambulance evacuation.

- **Life State Monitor (LSM)**

  The second desired configuration is the LSM which will use vital signs information to determine if a soldier is still alive, albeit wounded. If he is alive, then proper and determined efforts can be made to effect his rescue. If not, then valuable medical resources would be vectored to those in real need. This configuration would definitely require medical data transmission and must be designed specifically to be worn by the soldier prior to injury without impairing his performance. This requirement greatly increases the difficulty of system design. The life state monitor would need to measure the above mentioned VS and, in addition, would need to accurately assess the probability that the soldier was still alive and transmit that data to a squad leader or medic. Because of the nature of this vital decision device, diagnostic routines would have to be incorporated into the VSM. It would have to sense that the ECG electrode was properly attached but not receiving a life sign, that the SaO_2 sensor was functional but not seeing functional oxygen saturation, and that the device electronics were functioning properly. Obviously, if the life sign monitor was itself destroyed, then it could not verify that the soldier was still alive. The development of the LSM is a complex problem but Sarcos is confident of its ability to complete this task.

Sarcos Research Corporation (SRC) concludes from this Phase I study that it is both desirable and possible to build miniature VSMs to accompany the soldier from battlefield to hospital. It is also possible to build a LSM that would transmit a soldier's life status to a squad leader, medic. The challenge in such devices is measurement accuracy, wearability and compliance in the battlefield environment. However, Sarcos has had extensive experience in medical device development including the development of:

- Miniature, battery powered, disposable Infusion Pump (MicroJect).

- Miniature, long term, metered dose, battery powered, topical drug delivery system (PolyPulse).
- Implantable, battery powered, multiple metered dose drug delivery system.
- Miniature electrostatic and electromagnetic wobble motors
- Utah/VA artificial Arm
- Myolab, an electromyographic training instrument
- Iontophoretic drug delivery systems
- Uni-axial strain transducer (CMOS semiconductor device)
- Rotary displacement transducer (CMOS)
- Ultra-miniature CMOS multiplexed pressure transducer for the DARPA Integrated Sensor Network Project (ISNP)
- Advanced network concepts for ISNP
- Consultants for telemetry system development with Advanced Systems Technology Office/Electronic Systems Technology Office (ASTO/ESTO, Formerly ISTO)
- Wearable, portable artificial Kidneys

II. DETERMINATION OF DESIRED VITAL SIGNS

One of the first tasks that needs to be done in designing a vital signs monitor (VSM) is to determine what vital signs are most important. Obviously a plethora of information would be useful but could swamp medical personnel making triage decisions. SRC decided to talk with Army medical personnel to get firsthand input as to the most desirable vital signs.

Our technical contact at U.S. Army Medical Materiel Development Activity, Ft. Detrick, MD, Mr. Charles Paschal, suggested that we contact Major Joseph Hatch at the U. S. Army Medical Department, Center and

School at Fort Sam Houston who was evaluating VSMs for use in evacuation helicopters. Although we had hoped to meet with Major Hatch, that has so far been impossible. We have, however, had productive telephone discussions with him on several occasions. Major Hatch has had extensive battlefield medical experience. The four VS parameters that Major Hatch indicated were important were cardiac rhythm, heart rate, SaO_2, and blood pressure. He also stressed the difficulty performing any auditory examination, particularly in measuring blood pressures and diagnosing pneumothorax during evacuation by tracked vehicle or helicopter. Additional conversations with Major Hatch raised the following points: There was a need for a life detector with a transmit range of about 100 meters. Covertness is essential on the battlefield where indiscreet radio transmission could be used as a beacon by the enemy. However, during EVAC transmission is not particularly important. FAA compatibility and immunity from EMI were important considerations. He envisioned a monitor located on the wrist that could relay vital signs information to the squad leader and/or medic. He wanted information that did not overwhelm the medic thus detracting him from thinking properly about the patient's condition.

SRC had contacts at the Borden Institute and met with a group assembled by Dr. Don Jenkins at Walter Reed Army Medical Center. This meeting suggested the following parameters were important and useful. Perfusion of tissue as measured by SaO_2 was deemed the single most important vital sign. Other VSs included heart rate, respiratory rate and blood pressure. Temperature was not deemed particularly important. It was suggested that the most important environment for measuring these parameters included the primitive battlefield and subsequent evacuation to the hospital. Emphasis was placed on the noise and vibration encountered in evacuation helicopters and the fact the it was nearly impossible to measure blood pressure in this environment. Finally, emphasis was placed on the need to notice change in the patients condition rather than to be continually notified of stable vital signs values. It was further suggested that we talk to other individuals with real battlefield medical experience. The need for a device to detect whether or not a soldier was alive was also discussed.

These meetings and conversations suggest that vital signs of interest include SaO_2, ECG and thus heart rate, respiration rate and blood pressure. Heart rate can be obtained directly from ECG data or determined from pulse oximetry techniques used to measure SaO_2. Respiration rate can be recovered as an artifact on the ECG or measured using a strain gauge sensor located in an ECG electrode patch or both. Blood pressure (or at least changes in blood pressure) can be determined from the measurement of pulse wave travel time and R-R interval. Pulse wave travel time is determined as the delay from the peak of the R wave to the pulse pressure wave arrival time sensed at some remote site like the finger or wrist. Thus the important vital signs can be obtained from an ECG measurement and an optical SaO_2 sensor. An optional strain gauge could supply back up data for respiration rate.

All consultants agreed on and stressed the fact that the driving factors in the development of any battlefield medical device are the unique environments in which it must function.

III. REVIEW OF CURRENT VITAL SIGNS MONITORS

The review of current VSM monitors was not meant to be exhaustive but rather obtain information as to the state of the art and a sampling of available equipment and techniques.

A. TEMPERATURE.

The original proposal called for assessment of currently available temperature measuring devices. Although this was later determined to not be of much interest for the VSM, we did survey the market. Aside from the traditional mercury or electronic thermometers, many hospitals are using the non-contact infrared type thermometers. These remotely measure infrared energy emitted by the tympanic membrane. It is argued that the tympanic membrane temperature is a good measure of core temperature as it is perfused by the same vasculature that perfuses the hypothalamus, a regulator of body temperature. Intelligent Medical Systems Inc. market the FirstTemp, Genius model. Exergen Corp. has developed the Ototemp device. Both units cost several hundred dollars and are claimed to give reliable temperatures. Note that there are numerous IR temperature sensors used in industrial processes. The technology is well developed and mature.

While temperature may not be a particularly useful tool for vital signs it may play a role in the life monitor where a steady decrease in temperature could be one datum used to make a yes/no decision. There are numerous IC temperature sensors available such as the AD590 (Analog Devices) or the LM34 and 35 (National Semiconductor) which could be used for that application. Recently a solid state temperature sensor has become available that provides a direct digital output (TC620/21/26 by Teledyne Components).

B. ELECTROCARDIOGRAM (ECG)

Available ECG apparatus is almost too numerous to compile. We focused on either those units that could be used in an ambulatory mode or were part of an existing VSM system. Vitalog makes the Pocket Polygraph that can monitor and store (in non-volitile memory) many analog inputs including ECGs. Monitor One by Qmed is another example of an ambulatory ECG monitor. ECG monitors are built into many system packages and will be noted in that section.

C. PULSE OXIMETRY.

Many companies are marketing pulse oximeters. Palco manufactures several portable units for the home care market. Novametrix makes a unit specifically for clinical use while Omega has a combination PO/NIBP unit that uses a cuff, as does SpaceLabs, who use oscillometric techniques to measure BP. Other companies making pulse oximeters include Kontron, Radiometer Copenhagen, Ohmeda, Invivo and Biochem International. All units reviewed use optical sensing for determining SaO_2. This is a mature technology at this time. Sarcos anticipates no technical difficulties in incorporating this technology into an integrated product.

D. NON INVASIVE BLOOD PRESSURE (NIBP)

As mentioned above SpaceLabs measures NIBP using oscillometry. They also make an ambulatory unit that works with a small cuff inflated periodically by a miniature compressor, where detection is again by oscillometry. Invivo Research markets an AC/Battery operated unit that also uses oscillometry. Ohmeda has developed the Finapres unit that uses the principal of arterial unloading. In this scheme a small finger cuff has its pressure adjusted to maintain a constant arterial volume. This is done with a photoplethysmographic volume transducer and a fast servo controller. The pressure required to do this represents continuous blood pressure. The Finapres design team leader candidly admits that their device and the technology that drives it are on shaky ground.

There are numerous NIBP devices that use a small finger cuff and the oscillometric method. These are portable and are commonly sold mail order. One particularly remarkable device for estimation of NIBP is sold by Casio as their BP-100 wrist watch. This device uses calibration data, measurement of pulse pressure wave travel time and the R-R interval obtained from the ECG to estimate BP. This technique is discussed more fully in the next section.

E. VITAL SIGNS MONITORING PACKAGES

Several companies market vital signs monitor packages, some complete with radio transmitters. Protocol Systems make a Propaq 106 EL package that weighs 6 pounds and is available with ECG, NIBP, IBP, SpO_2 and temperature. Protocol's president claims this unit can oscillometrically measure blood pressure in a helicopter (personal communication). Mennen Medical manufactures a line of VSMs and recorders that measure most of the common vital signs although not all are available on a single chassis. Medical Data Electronics has their Escort series of VSMs. These units incorporate radio telemetry for use in local areas. The Escort series provides most of the common vital signs parameters. Datascope Corporation makes their Passport line of physiological monitors which contain most of the vital signs measurements required in this project. Finally, there is the Pace Tech 911 Minipack. This is a light weight unit designed for the EMS environment. All of the above mentioned VSMs measure BP with the aid of an inflatable cuff.

IV. REVIEW OF TECHNOLOGIES APPROPRIATE TO THIS PROJECT

The review of current VSM technologies provides a background of techniques that might be used in the development of a miniature vital signs package. A serious effort was made to search the current literature, patents and product information so that the best techniques could be determined.

A. ELECTROCARDIOGRAM (ECG)

Our literature review revealed several specialized applications of ECG telemetry and provided information useful for the proposed VSM. Barnea and Deutsch (1986) describe a relatively simple telemetry system that uses the gates of FETs at the input electrode thus providing high impedance inputs and minimizing noise. Sarcos [Jacobsen, et al., (1982)], has achieved excellent results with miniature electromyographic preamplifiers for the Utah arm. Thackor and Webster, (1980), modeled a ground free two electrode system for recording ECGs. The model shows that reasonable ECG records can be made with two electrodes and provides a basis for system design. Fryer, et al., (1975), developed an implantable multichannel telemetry system and evaluated the possibility of using a microimplantable VSM, as was the work of Suess and Goiser, (1986). Other reviews included papers by Murray, et al., (1968), and Kamp, (1984).

For this report, our recommendation is to extend the technology represented by the electromyographic preamplifiers described above and previously developed at this laboratory. The ECG amplifiers must be robust, high input impedance devices with integral defibrillation protection circuits. Extrinsic noise caused by sources of nearby electromagnetic fields such as electric motors, radios, medical equipment and etc., can mask many diagnostic features of the ECG. The use of integrated electrode/preamplifiers or conventional electrodes with preamplifiers in close proximity will minimize this type of artifact. It is further recommended that, to insure stable ECG monitoring, a form of dry Ag-AgCl electrodes be used. This can be achieved quite simply with small, durable, chlorided silver disks. Since, for ease of use and personnel compliance, it is desirable to use a single, two electrode lead array, it is important to select that lead with the greatest diagnostic utility for the anticipated types and frequencies of injury. Extensive blood loss due to trauma, non-bleeding cardiac damage such as aneurysm or compression trauma, and ischemia are best identified by their effect on ST-T displacement and/or on T-wave form. A left-lateral ECG lead is suggested for sampling such changes in waveform (similar to Lead V or VI).

VSM ECG AMPLIFIER AND R-WAVE TRIGGER

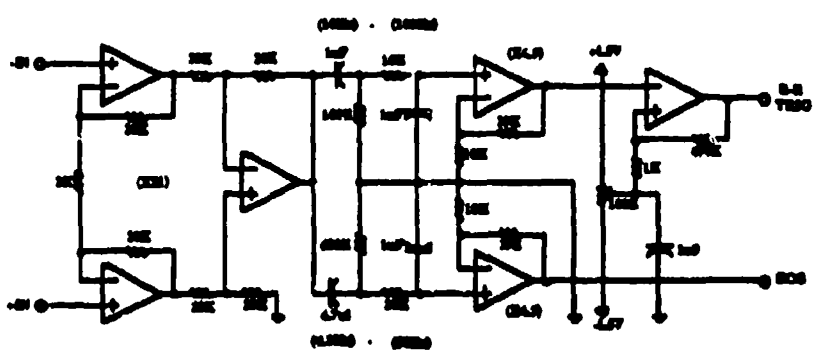


Figure 1. Prototype ECG Amplifier with separate r-wave trigger output.

An R-wave trigger is required elsewhere in the proposed VSM to measure heart rate and blood pressure. Analog filtering will provide clean narrow band R-wave signals for detection by a voltage comparitor. A filter with conventional ECG bandpass will provide high quality signals for analog to digital conversion and subsequent data analysis. An appropriate circuit diagram is shown in Figure 1.

B. SaO_2 MEASUREMENT BY PULSE OXIMETRY

Pulse oximetry is a very common technique used to determine arterial oxygen saturation (SaO_2). Presently optical sensors measure the ratio of absorbance of two different wavelengths of light transmitted through the end of the finger, or toe (660 nm and 940 nm are frequently used). Only the AC component, which is due to the pulsatile arterial flow, is used. This eliminates the absorption components due to venous blood and digit tissue. Usually an ambient light measurement is also made to correct for background illumination. Figure 2., shows absorption curves for hemoglobin, oxyhemoglobin, melanin and water. Sarcos suggests the use of absorption measurements at 660 nm and 940 nm. The absorption coefficient for melanin is somewhat constant over this range and, for water, is an order of magnitude less.

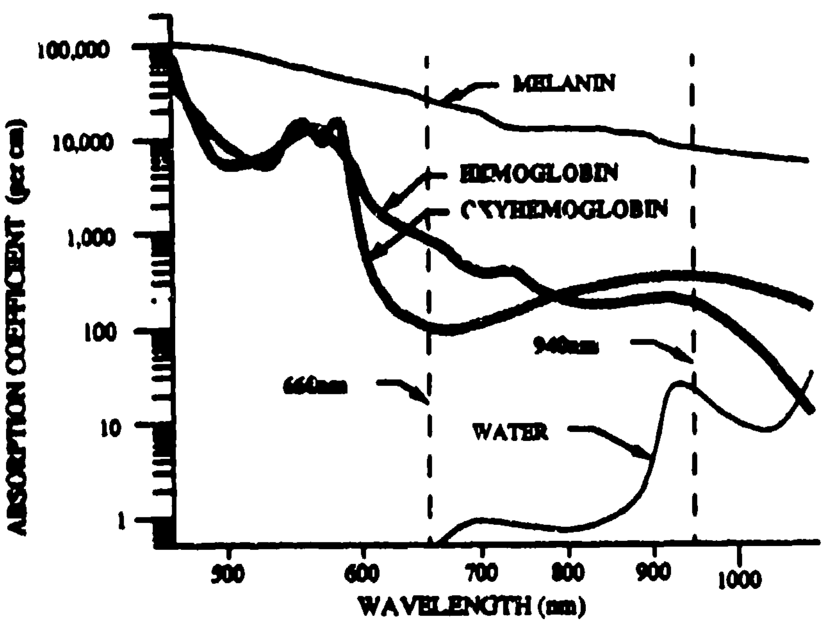


Figure 2. Absorption coefficients for hemoglobin, oxyhemoglobin, melanin and water.

Figure 2., also demonstrates the crossing of the absorption coefficients for hemoglobin and reduced hemogloben (oxyhemoglobin). It is a feature that makes the measurement of SaO_2 by oxymetric methods practical in broad variety of conditions and environments.

Oxygen saturation is a function of the ratio of the absorption of infrared (IR) radiation at two wavelengths by arterial blood.

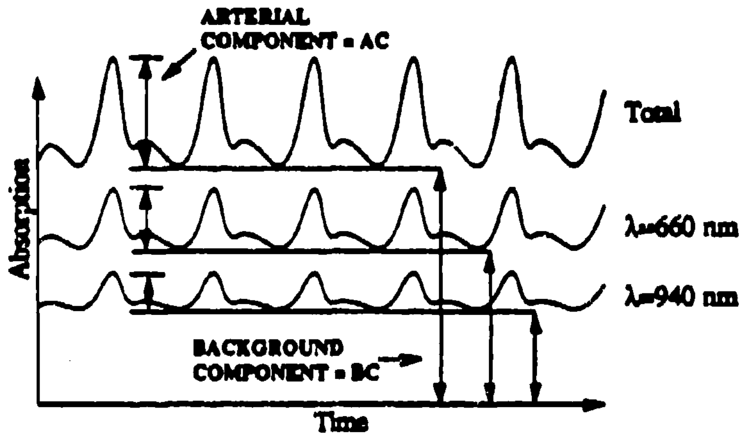


Figure 3. Representative absorption waveforms for SaO_2 measurements (simulated).

The pulsatile signal from the detector represents arterial blood oxygen saturation level. Representative waveforms showing the time course of absorption broadband (total) absorption and at the two wavelengths of interest are shown in Figure 3. The background components are caused by external illumination and absorption due to non-variable components of blood, bone and tissue. Data obtained from measurements as shown in Figure 3., are used to determine a ratio R, as defined by Equation 1.

$$R = \frac{(AC_{660} / BC_{660})}{(AC_{940} / BC_{940})}$$

Equation 1. Relationship of R to measured absorption values.

Figure 4., illustrates the nonlinear relationship between the ratio R, and percent arterial oxygen concentration. It is important to note that each pair of wavelengths (in this case 660 nm and 940 nm) will generate a different curve for the ratio due to differences in molar extinction coefficients.

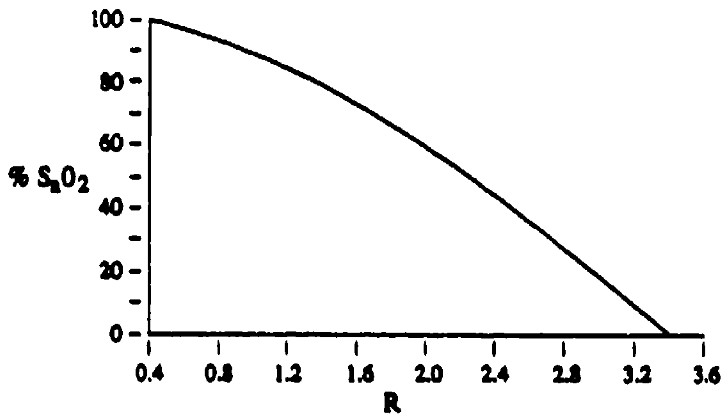


Figure 4. Relationship of the ratio R, to Percent SaO_2.

A proprietary look-up table is then used to provide SaO_2 values. This table is derived empirically from the same calibration data as that shown in the curve of Figure 14.

Recently, scattered light has been used in a commercial instrument to measure SaO_2 in the brain through the skull. The technical approach for this method is more complex but certainly feasible. Much attention has to be placed on illumination angle and separation of the photo sensor and light emitters. Using either the above described techniques or the absorption of light traversing the space between the radius and ulna, Sarcos feels that a wrist mounted SaO_2 sensor is possible. The same sensor would, of course, provide pulse pressure wave (PPW) measurements to be used for non-invasive blood pressure determination. We propose using circuitry similar to that shown in figure 5 to obtain photometric data. For this circuit and the ECG amplifier circuit described previously, all potentiometers or other adjustable components will be replaced with automatic gain and automatic level control.

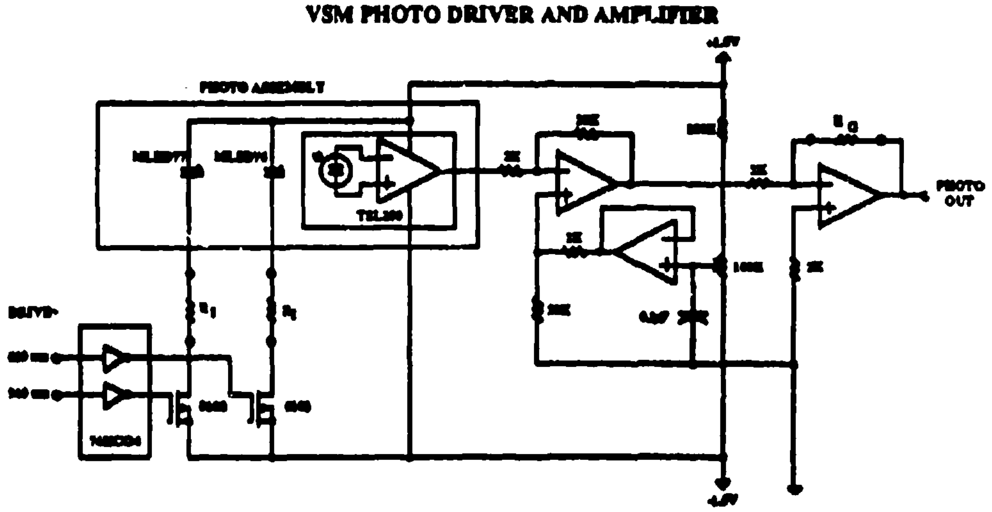


Figure 5. Circuitry for prototype device to obtain photometric data.

The microprocessor in the VSM system control system will generate appropriately timed drive pulses to excite IR sources emitting at 660 nm and at 940 nm. Timing parameters for driving the IR emitters and convert commands (sample time) for the time multiplexed analog to digital converter are shown in Figure 6.

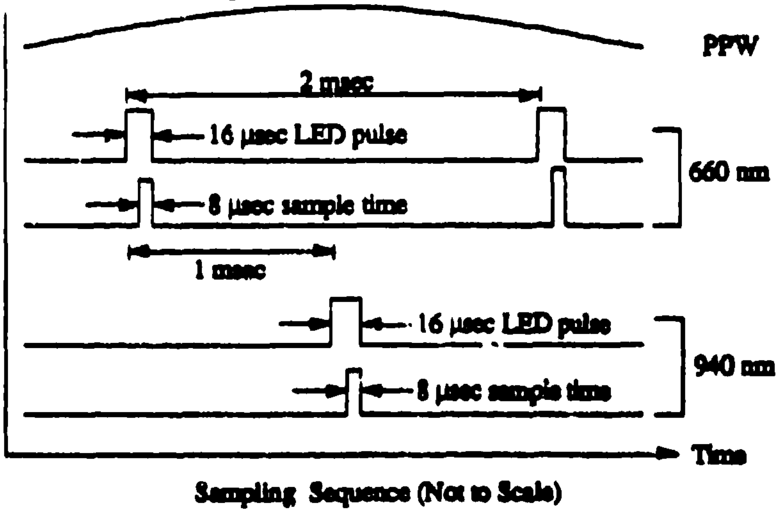


Figure 6. Timing sequence for for sampling and analog to digital conversion of photometric data.

Photometric measurements generally require considerable energy emission for low noise detection and will do so particularly if through-wrist sensing is used. Excitation at approximately 500 Hz provides an adequate sampling rate for pulse waveforms and the very narrow excitation pulses (15 μsec) will permit low battery power drain and a duty cycle of about 1.6 percent.

C. RESPIRATION RATE

Respiration rate can be obtained in two ways for the proposed VSM. Direct determination of respiratory rate can be made using a strain gauge as part of the ECG chest electrode patch. The patch would be made out of an elastomeric material with a strain gauge attached to the material. As the soldier breathed the strain gauge would sense respiratory expansion and contraction. Filtering would remove high frequency muscle tremor artifact. Software algorithms would determine rate from clean data after discarding artifact and questionable data. The rate determined this way would be compared to respiratory rate recovered from ECG artifact. Low frequency signals associated with breathing would be digitally sampled from the ECG waveform with peak following operators in software. This recovered signal would be compared with that measured by the strain gauge and if the correlation was good then that data would represent the respiration rate.

D. NON-INVASIVE BLOOD PRESSURE

Blood pressure can be measured either invasively or non-invasively. Invasive measurements involve the direct contact of a pressure transducer with the arterial system. This usually involves the insertion of a cannula into an artery. The cannula is connected to a pressure transducer to effect the measurement. Invasive methods provide a high degree of accuracy and repeatability but impose a significantly greater risk and inconvenience to the patient than do non-invasive techniques. Non-invasive measurement of blood pressure does not require penetration of the body, yet most methods provide sufficiently reliable values to to be a valuable diagnostic tool. Over the years a variety of non-invasive techniques have been developed.

Most of the techniques involve altering the shape of an artery by applying some external pressure and measuring that pressure. For example, the most common non-invasive method uses an inflatable cuff to occlude the artery by compression and then releasing the pressure slowly and noting the pressure when the flow of blood resumes and when the flow becomes nonturbulent. This method, called sphygmomanometry, is based on the detection of Korotkoff sounds or measurement of flow by ultrasound. Other methods include tonometry, oscillometry and vascular unloading. Recently a new technique which employs pulse pressure wave travel time and heart rate has shown promise and there is even a commercial product that uses that method.

Sarcos surveyed the literature in search of a method for estimating BP that could be done without a cuff and in a noisy environment such as a battlefield of evacuation helicopter. Talke, et al., (1988), showed that they could measure systolic BP with a cuff and a pulse oximeter to determine the onset of flow in the noisy helicopter environment. Thus demonstrating that optical methods are relatively immune to vibration artifact. Unfortunately, for the VSM design that we envision, an arm cuff cannot be used. Wood, et al., (1950 a,b), developed a miniature ear cuff and used ear opacity as a measure of re-establishment of blood flow. With their technique they could estimate both systolic and diastolic pressures. Again the technique would not be particularly suitable for the battlefield. Pressman and Newgard, (1963), and Kemmotsu, et al., (1991), have devised and evaluated a tonometer that uses compression of the radial artery to determine both blood pressures. Their device is available commercially (Colin Electronics Corp) but the problems of relatively precise placement of the sensor and motion artifact preclude that technique from use in the military VSM. The vascular unloading approach devised by Penaz, (1973), and evaluated by Yamakoshi, et al., (1983), again uses a finger cuff and would not be suitable for battlefield use. Adams, et al., (1960), devised a wrist mounted detector that used measurement of capacitance to estimate BP. This method is subject to considerable motion artifact.

As alluded to above, Sarcos sought to find a cuffless method to measure blood pressure non-invasively. Literature review did indeed reveal a technique that reliably measures changes in blood pressure and can if calibrated give a useful estimate of actual diastolic and systolic pressure. Bramwell and Hill, (1922), measured the velocity of the pulse pressure wave (PWV) in man. They found that the velocity of the PWV was dependent upon the blood pressure. Their work was followed up by that of Hemingway, et al., (1925), who found that pulse velocity/extensibility/pressure relationships were good down to about 40 mmHg and that diastolic pressures could be estimated. Others including Hallock, (1934), Haynes, et al., (1936), Steele, (1937), Yoshimura, et al., (1968), Nye, (1964), and Weltman, (1964), correlated PWV with arteriosclerosis and advocated its use as a diagnostic tool. Others including King, et al., (1972), and particularly Carruthers and Taggert, (1988), reported correlations between PWV and blood pressure. Orr and Carruthers, (1989), and Trimmer and Slechta, (1981), filed patents for apparatus to measure blood pressure using PWV. Finally, Casio Inc. markets a combination watch, blood pressure indicator and heart rate monitor for about $150. The device called the BP-100 has been evaluated in two unpublished reports, Matsumoto, (1991), and Ishimitsu and Yagi, (1991). If calibrated with data taken with a standard sphygmomanometer the BP-100 gives a good estimate of blood pressure (see Figures 7., and 8.). Sarcos proposes to adapt a similar method into a miniature VSM since the method appears to be relatively immune to acoustic noise and vibration and could provide useful information even during helicopter evacuation.

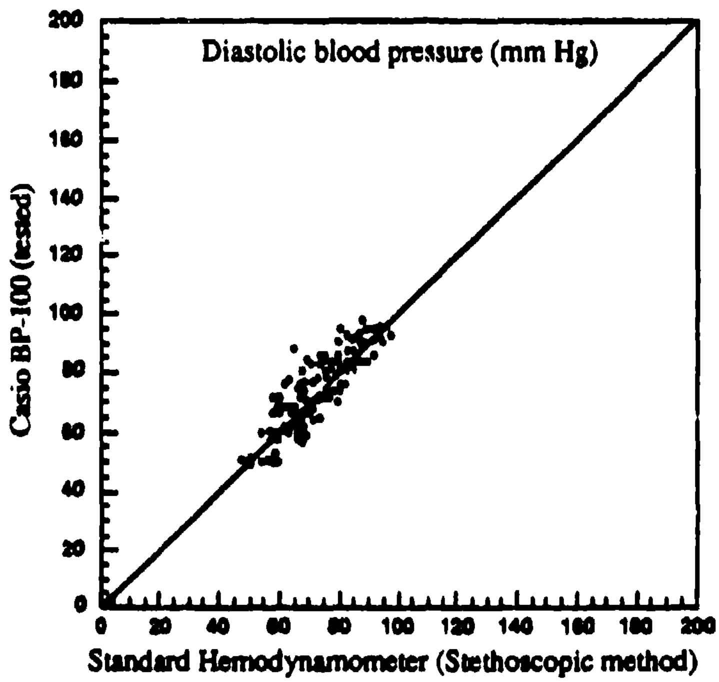


Figure 7. Comparison of diastolic blood pressures obtained using PWV method (Casio BP-100) and sphygmomanometric method.

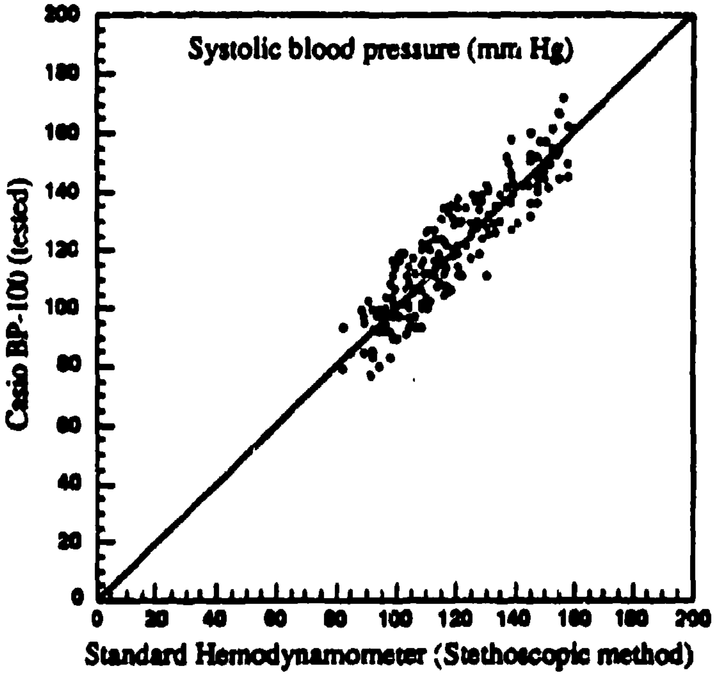


Figure 8. Comparison of systolic blood pressures obtained using PWV method (Casio BP-100) and sphygmomanometric method.

A typical output voltage waveform from an infrared emitter-detector pair placed over the radial artery is shown in Figure 9. The tall peaks in the waveform correspond to pulse pressure wave (PPW) peaks.

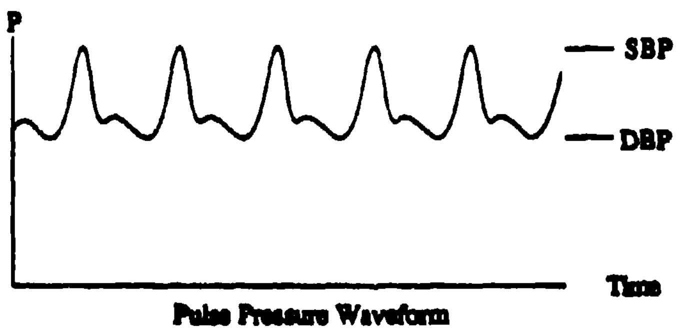
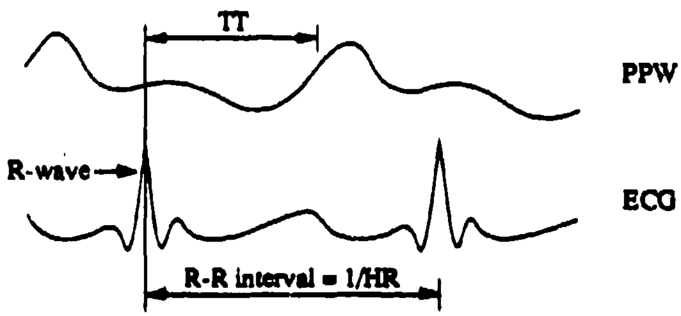


Figure 9. Representative pulse pressure waveform (simulated).

Figure 10., illustrates the derivation of the detected pulse pressure wave and R-wave timing relationships required for NIBP monitoring. The fiducial points for two measurements are determined by sensing peaks of the PPW and ECG waveforms with voltage comparitor type level detectors. The peak of the R-wave generally occurs at the time of depolarization of the largest mass of left ventricular muscle, a noninvasively detectable event which closely corresponds to the initiation of the PPW for a given cardiac cycle. The PPW traverses the subjects vasculature at a rate largely determined by the cross-sectional dimension of the artery, the arterial extensibility and the blood pressure. The measurement, TT corresponds to the transit time of the PPW from the heart to the point of measurement. The R-R interval is directly measured from the R-wave peaks. Heart rate, HR is simply the inverse of the R-R interval. All times and relationships are calculated from measured data by the by the microprocessor in the VSM controller.



Relationship of Pulse Pressure Wave to ECG

Figure 10. Simulated waveforms for blood pressure measurement

Equations 2., and 3., are used to obtain diastolic blood pressure, DBP, and systolic blood pressure, SBP, respectively. The suffix "r" denotes reference values obtained during the enlistment physical and updated during subsequent physical examinations (i.e., HRr=reference or "control" heart rate.

$$DBP = \frac{3(TT \times HR - TTr \times HRr)}{(134 \times HRr) - (0.78HRr \times TTr) - \frac{8750 \times HRr}{TTr}} + DBPr$$

$$SBP = -0.8(TT - TTr) + SBPr$$

Equations 2, and 3. Relationships for estimating systolic and diastolic blood pressure

E. VSM TRANSMITTER

At least one form of the VSM requires that data be transmitted over a limited range. We therefore have investigated various transmission schemes. The proposed VSM transmitter module is optional depending on the device configuration. It would perhaps not be used on the finger based sensor package designed primarily for EVAC use, but would most likely be used on the life detector and on the wrist based VSM.

In this particular area, Sarcos again considers it important to collaborate with experts from the U. S. Army. Design decisions in communications methods must be made in conjunction with infantry (war fighters), and representatives from the military communications arena. Considerations such as transmission security, compatibility with existing land and air ambulance and field hospital communications and other factors must be discussed early in Phase II of this project. An example of the technology that can be used follows. An FM transmitter module such as the Motorola MC2833 could be employed. This device is a single chip transmitter requiring few external components, mostly capacitors and resistors. These components would require minimal space if implemented with miniature, surface mount devices. Transmitter dice of this general type are small and the entire transmitter, employing hybrid circuit techniques, would occupy a few cubic centimeters. The transmitter would be capable of up to 10 mW output, more than adequate for the limited range desired. Data could be sent asynchronously using AFSK tones to a central, frequency scanned receiver. Data would include identification number or name, time, vital signs of interest or a probability estimate of life.

With additional complexity, the addition of a small receiver and data processing circuitry, two way communication could be possible. Motorola makes a complimentary receiver chip, the MC3363 which, with the MC2833, could provide transceiver operation. The advantages of transceiver capability include: the ability to query the soldier's system to verify proper operation or status of the soldier; the ability for the soldier to send and receive messages to/from the squad leader. While the system could have voice capability a simpler approach might be to use programmed messages such as #1, "I am OK", #2,"I am injured" or #3, "Need ammo" etc. With transceiver capability a packet like data transmission system could be implemented, complete with data error checking. The packet system could operate on a single frequency. Note that this communications system would operate over only a very limited range of a few hundred meters. With this system a squad leader could keep track of members of his squad and be apprised of their medical condition. One additional feature of a limited range communications beacon might be to help recognize friendly troops. Figures 11, and 12, illustrate the simplicity of a possible two chip transceiver.

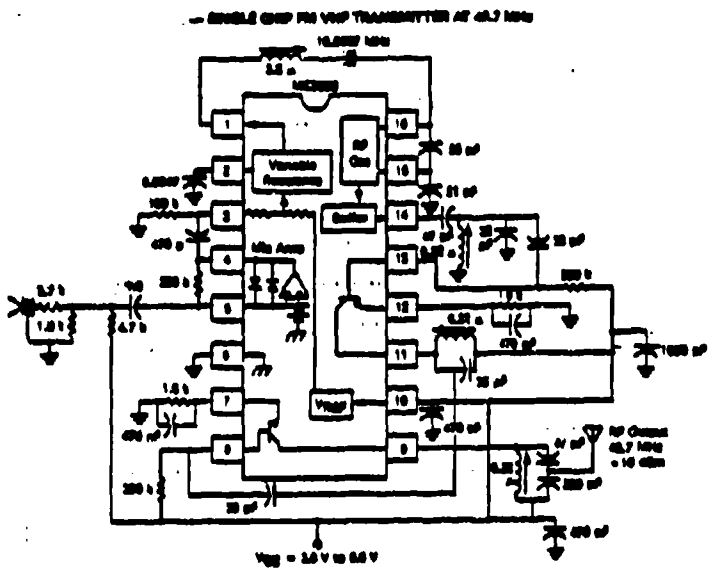


Figure 11. Schematic for one possible configuration of a single-chip transmitter

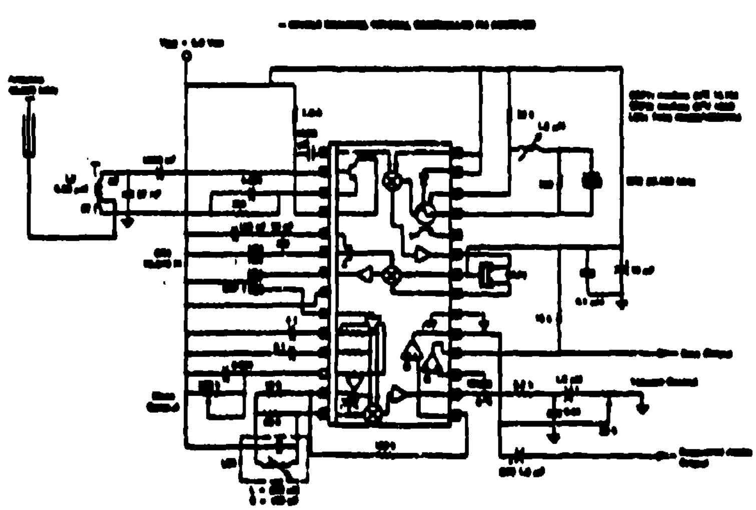


Figure 12. Schematic for one possible configuration of a single-chip receiver

F. VSM SYSTEM CONTROL

Sarcos presently uses the 68HC05 series microcontrollers on several of its medical projects. For example we have developed and brought to market an iontophoretic drug delivery system which employs a 68HC705C8 microcontroller and are developing a low cost, disposable infusion pump for which we have selected the 68HC705P9 version as the prototype controller. This particular microcontroller has a 4 channel 8 bit A/D converter, 2112 bytes of EPROM, 128 bytes of SRAM, and power saving STOP, WAIT and data retention modes. Depending on system system complexity, additional SRAM may be required. However, memory is physically small and adding more would not significantly increase the VSM volume. This or a similar M68HC05 series microcontroller would be suitable for the Phase II prototype development. Sarcos has the programmer, debugger, some software, an emulation board and considerable experience with this controller series.

V. PROPOSED VITAL SIGNS MONITOR CONFIGURATIONS.

There are several possible configurations for the miniature VSM, in fact it might be desirable to construct two or more versions to satisfy particular requirements. Determination of the precise configuration and associated modules should be done with the collaboration of Army Medical personnel. Sarcos therefore proposes that the VSM sensors and associated signal processing electronics be based on modular hybrid circuit units so that different versions can be easily configured and tested.

Sarcos has also developed full CMOS integrated circuit design and layout capability and has fostered an excellent working relationship with Orbit Semiconductor whose foundry we use for fabrication. It would be a logical extension of this project to integrate as much as possible of the VSM circuitry.

Figures 13. is an example of Sarcos' capability in hybrid circuit design. The pictures of a complex integrated circuit die (chip) shown in Figure 14., is an example of a functional, large scale integrated (LSI) circuit that Sarcos has designed for integrated sensor applications.

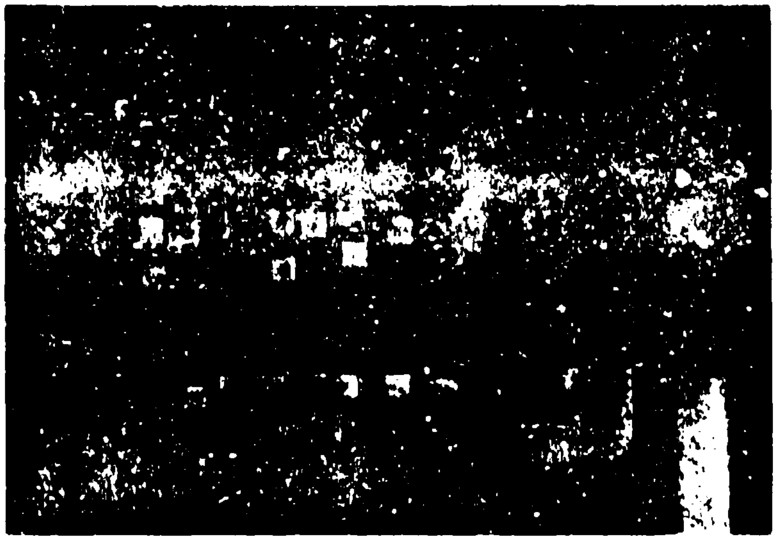


Figure 13 Hybrid circuit pulse width modulator for Utah/VA Arm

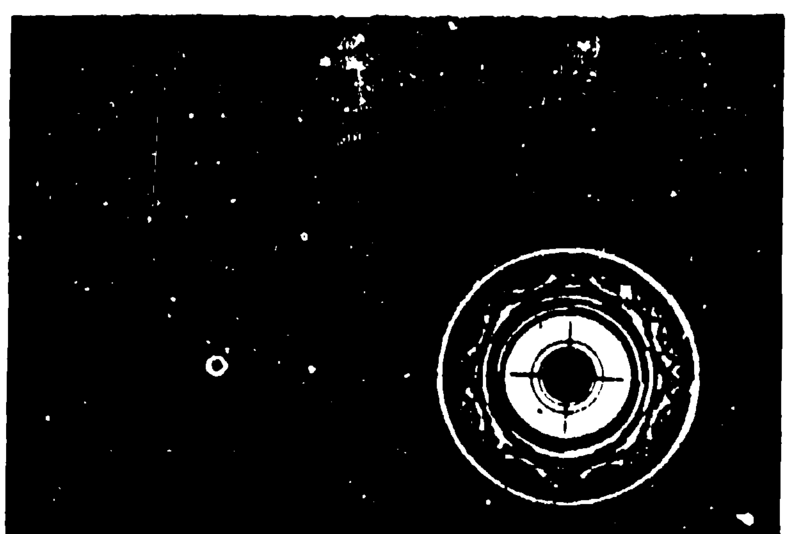


Figure 14. Integrated rotary sensor (left) and sapphire emitter for sensor sputtered and patterned using in house micro-photolithographic techniques

A. VSM, FINGER COT VERSION

A concept drawing of the finger cot based VSM is shown in Figure 15. This configuration would contain a device for trans-finger optical sensing of SaO_2 by pulse oximetry. The pulse data would be used in conjunction with ECG signals to determine pulse wave travel time and thus be used to determine changes in blood pressure. If calibration data were entered, then an approximately correct blood pressure for that individual would be indicated. The finger cot device would also contain one of the ECG electrodes, the other electrode would be applied to the chest (or, if necessary, to the opposite wrist) and connected to the cot device. This special electrode would have a strain gauge built into the adhesive patch so that respiration rate could be measured (if attached to the chest). This set of sensors thus gives SaO_2, ECG, heart rate, respiration rate, and a measure of blood pressure.

VSM, FINGER COT IMPLEMENTATION

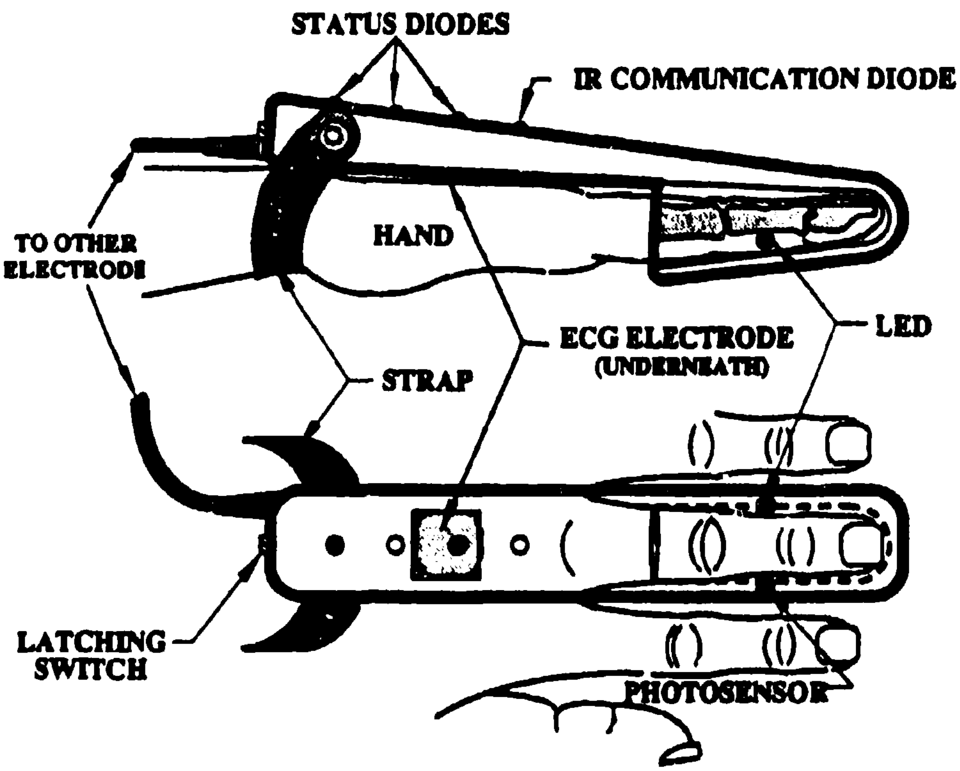


Figure 15. Concept drawing of VSM finger cot implementation.

The finger cot VSM would be fitted with either an LED array indicating status (idiot lights) and/or an LCD screen which would indicate VS values or indices. A presettable audio and visual alarm would indicate a predetermined change in the patients status. These indicators, perhaps a small keypad and the main electronics package would be located above the back of the hand. A securing wrist strap would prevent the finger cot from becoming detached from the patient and additional stabilization of the patients arm could be made to the patient's chest or abdomen during transport allowing the VSM indicator lights to be clearly visible. The finger cot version of the VSM is the type of device that could be carried in quantity in the medic's aid bag for battlefield application. In addition, if a "clamshell" variant on the proposed design shown in Figure 15., were implemented with the electronic emitters, sensors and electrodes mounted in the lumen of a needles, then a medic could obtain vital and or life signs by puncturing the gloves of soldiers in full MOPP level IV attire. The second ECG electrode could double as a needle for use with an auto-injector to atropinize a contaminated soldier. The small holes (approx. #18 gauge) would be somewhat self sealing and represent minimal violation of the MOPP environment.

The finger cot version of the VSM would be the easiest configuration to implement in terms of SaO_2 sensing since the mature technology of transdigit optical sensing is used.

B. VSM, WRIST VERSION (WVSM)

The wrist version of the VSM (WVSM), worn much like a wristwatch, would allow the soldier to wear the device before becoming injured thus precluding the need for field installation by medical personnel or the critical decision by untrained soldiers to install and use the VSM. In this version of the VSM an optional radio transmitter could supply data to a central point.

The wrist version of the VSM would also be based on modular sensor units. Miniaturization here would be more important than in the finger cot version, since the"watch" would have to have a low profile so as to cause minimum interference with the mission of the soldier.

Here, the optical sensing of SaO_2 and PPW would be done by sensing scattered or transmitted light. Techniques involving scattering require more sophisticated instrumentation to provide higher gain and also to minimize extrinsic noise and motion artifact. The WVSM would also have a single external electrode for sensing ECG and respiration. The second ECG electrode would be on the back of the "watch" as is the electrode on the Casio BP-100. The optical sensor for pulse oximetry could function by sensing the scattering of light or possibly by light transmitted through the space between the radius and ulna. Near the wrist both the posterior and anterior interosseous arteries "surface" to pass over the carpal bones. It may be possible with a sufficiently intense light source to use transmitted light to sense SaO_2 in vessels in the interosseous space. Figure 16. is a block diagram of the WVSM.

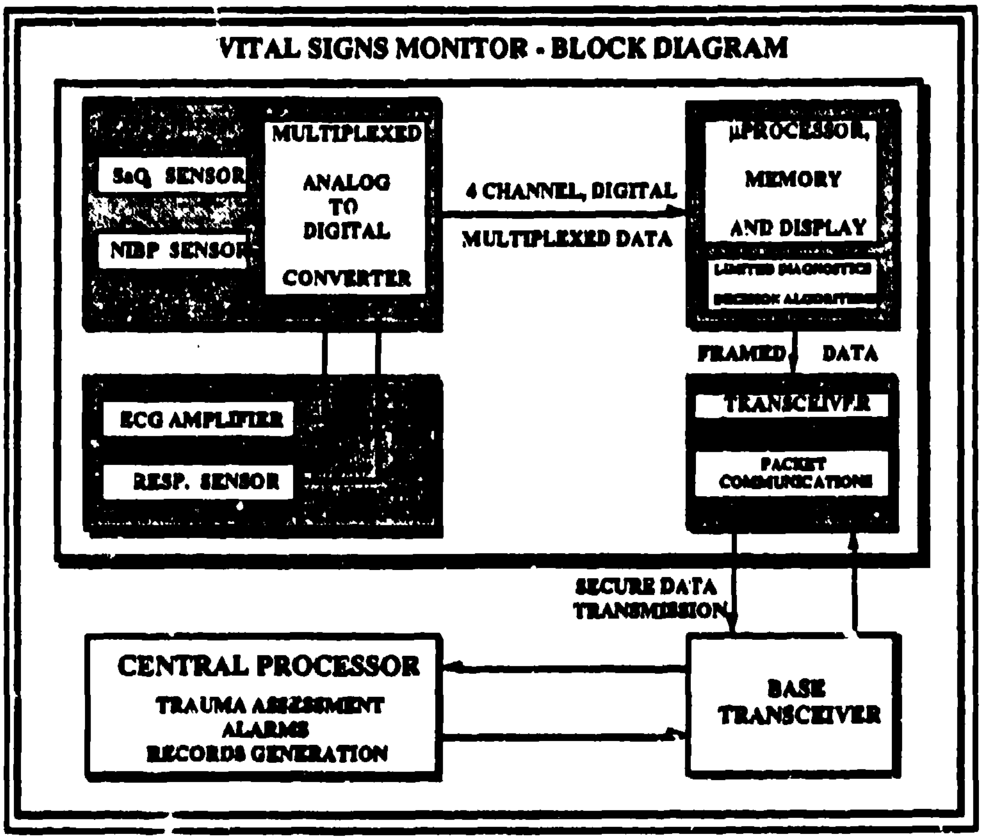


Figure 16. Block diagram of wrist watch implementation of the WVSM

Figure 17. is a concept drawing of a possible implementation of the WVSM.

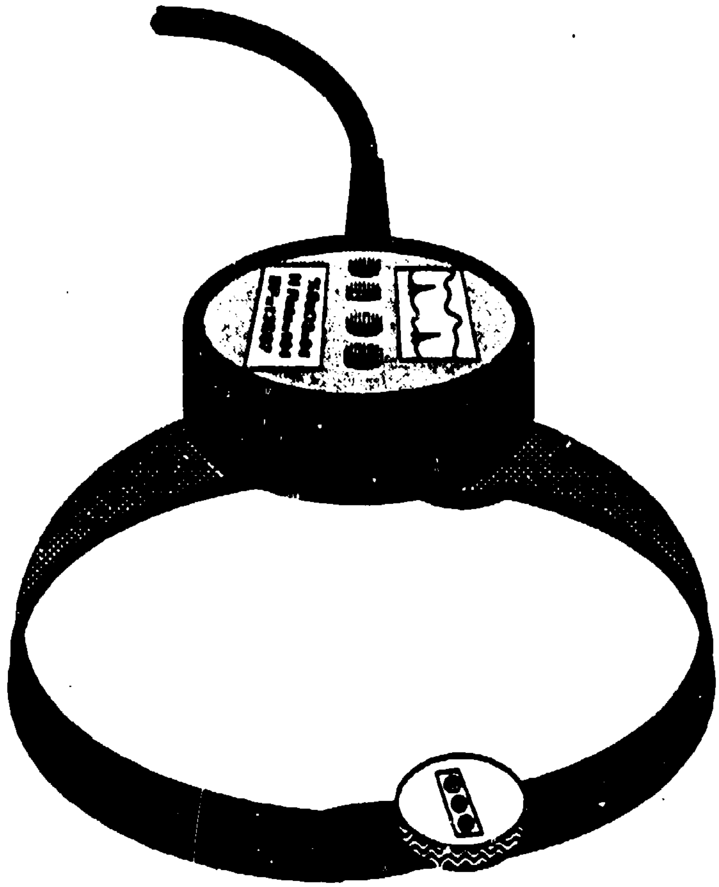


Figure 17. Concept drawing of wrist watch version of the WVSM

The U. S. Army's development of the "electronic" dog tag has been discussed in several electronics periodicals. This dog tag contains a small memory chip, a battery and an electrical connector or a magnetic device to convey data in and out of the card. It has been determined that some form of medical data will reside in non-volatile memory in the dog tag. The VSM could easily contain complimentary devices to retrieve reference data for blood pressure monitoring and also, if conditions warrant, to input measured data into the dog tag.A particular advantage of the WVSM is that it could be worn while attired in full MOPP level IV protective gear, in tank suits, flight suits, battlefield dress and in future exoskeletal systems.

C. LIFE STATE MONITOR (LSM)

The customer has indicated the need for a device to determine whether a soldier is dead or alive and relay this information back to the medic, squad leader or other mission leader. Such a device would need to determine vital signs to make this assessment. It appears that, with modification, the functionality of the VSM outlined above could be extended to provide this additional utility. Certainly a device measuring vital signs could also transmit the single datum that the soldier was indeed alive. If the device found no vital signs and it could be determined that the device was operational with its sensors in proper operating condition, then it would use specific algorithms to determine the probability of the soldier being alive. If that probability falls below a threshold value (to be determined), then it would, with confidence, transmit that the soldier is dead. If any other sets of conditions occurred and the LSM had insufficient information to make a confident decision, it would transmit probabilistic data as to life or death. Certainly if the soldier was alive and this could be determined by the LSM, then appropriate rescue efforts could be initiated. As previously mentioned, The LSM data transmission must be covert. Data would be transmitted, infrequently for short distances as a short (less than one second) burst of data Sarcos feels that the development of the life signs monitor would be a natural extension of the development of a VSM.

Although outside the scope of the current VSM proposal, Sarcos would like to stimulate interest in a very possible future enhancement to VSM/LSM concept. Specifically, incorporating Global Position System (GPS) technology into the device communications package. The development of this enhancement implies the use of a much more sophisticated base station. For example, a adaptation of the popular notebook type portable computer package could be used. The flat screen display of this device could accept or generate specific battlefield map overlays. In this fashion, patrol leaders, battlefield command posts and corpsmen could instantly view location, condition and activity level (derived from vital signs data) of all soldiers.

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SUPPLEMENTARY

INFORMATION

DEPARTMENT OF THE ARMY
U.S. ARMY MEDICAL RESEARCH, DEVELOPMENT, ACQUISITION, AND LOGISTICS COMMAND (PROVISIONAL)
FORT DETRICK, MARYLAND 21702-5012

REPLY TO ATTENTION OF

ERRATA

SGRD-RMI-S (70-1y) 1 Nov 94

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LTC, MS
Deputy Chief of Staff for Information Management

ERRATA

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